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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,451

06/05/2006

Francois Ichas

REGIM 3.3-073

8046

530 7590 09/02/2009  
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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

09/02/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,451	<b>Applicant(s)</b> ICHAS ET AL.	
	<b>Examiner</b> CHRISTIAN L. FRONDA	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 8-25 and 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/17/06</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicant's election with traverse of Group I (claims 1-7 and 26) in the reply filed on 04/27/2009 is acknowledged. The arguments filed 04/27/2009 have been considered but are not persuasive because the marker protein of Wolter et al., such as GFP fused to Bax, Bcl-2, and Bcl-X<sub>L</sub>, was shown to be a direct marker for the occurrence of an apoptotic event and thus can be used in the recited claimed methods. As previously stated, a same or corresponding technical feature shared among Inventions 1-12 is a marker protein for use in the method recited in claim 1 for the demonstration of the occurrence of a specific molecular event in a cell. Thus, the same or corresponding technical feature is not special since it was known in the prior art and therefore cannot make a contribution over the prior art. Since the inventions lack the same or corresponding special technical feature, then the inventions listed as Inventions 1-12 are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 8-25 and 27-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-7 and 26 are under consideration in this Office Action.

### ***Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-7 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase “(respectively the binding of a solubilized marker protein)” which renders the claim vague and indefinite. The metes and bounds of the claim are uncertain

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because it is unclear if the claim is actually limited to the subject matter within the parenthesis. Dependent claims 2-7 and 26 are also rejected because they do not correct the defect of claim 1. Appropriate correction is requested.

***Claim Rejections - 35 U.S.C. § 112, First Paragraph***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-7 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the demonstration of the occurrence of an apoptotic event in a cell comprising detecting the presence of the GFP fused to the N-terminal of Bax comprising the amino acid sequence of SEQ ID NO: 2; **does not** reasonably provide enablement for other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

According to MPEP 2164.01(a), factors considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue” include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

MPEP§ 2164.04 states that while the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not

necessary to discuss each factor in the written enablement rejection. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. Accordingly, the factors most relevant to the instant rejection are addressed in detail below.

The nature and breadth of the claims encompass any method for the demonstration of the occurrence of any specific molecular event in any cell comprising detecting the presence of any marker protein in the cell.

The specification provides guidance, prediction, and working examples for a method for the demonstration of the occurrence of an apoptotic event in a cell comprising detecting the presence of the GFP fused to the N-terminal of Bax comprising the amino acid sequence of SEQ ID NO: 2. However, the specification does not provide guidance, prediction, and working examples for making and/or using the invention as claimed.

Thus, one skilled in the art must perform an undue amount of trial and error experimentation which includes searching and screening for any marker protein to present in any cell, modification of any marker protein to be detectable in the cell, and searching and screening for any specific molecular event in any cell which can be detected by the presence of any marker protein. General teaching regarding screening and searching for the claimed invention such as using enzyme activity assays is not guidance for making the claimed invention. Therefore, in view of the overly broad scope of the claims, the specification's lack of specific guidance and prediction, the specification's lack of additional working examples, and the amount of experimentation required; it would require undue experimentation for a one skilled in the art to make and/or use the invention commensurate in scope with these claims.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-7 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolter et al. (J. Cell Biology, Vol. 139, No. 5, Dec. 1, 1997, pp. 1281-92; reference CK in the IDS filed 07/17/2006).

Wolter et al. teach a method for the demonstration of an apoptotic event in a cell comprising the binding of solubilized marker protein, such as GFP fused to Bax, Bcl-2, and Bcl-X<sub>L</sub>, which is a direct marker for the occurrence of an apoptotic event, where the marker protein is present in the cell before the detection; and the presence of the marker protein being detected in the cell by any appropriate means including fluorescence microscopy, which makes it possible to determine whether binding and thus apoptotic event has occurred (see entire publication and abstract, especially pages 1281-1286). Thus, the reference teachings anticipate the claimed invention.

### ***Conclusion***

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/

Primary Examiner

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